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| 10/516,504 | 12/02/2004 | Hiroyuki Mizuguchi | 081356-0226 | 8630 |
| <div>22428 7590 06/18/2007</div> <div>FOLEY AND LARDNER LLP</div> <div>SUITE 500</div> <div>3000 K STREET NW</div> <div>WASHINGTON, DC 20007</div> | | | | |
| | | | EXAMINER | |
| | | | MARVICH, MARIA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1633 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 06/18/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/516,504

Applicant(s)

MIZUGUCHI ET AL.

Examiner

Maria B. Marvich, PhD

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 8-11 and 13-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 12 and 18 is/are rejected.
- 7) ☒ Claim(s) 7 and 19-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/2/04; 12/20/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I(claims 1-7, 12 and 18-21) in the reply filed on 4/26/07 is acknowledged.

Claims 8-11 and 13-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/26/07.

Information Disclosure Statement

An information disclosure statement filed 12/2/04 has been identified and the documents considered. The corresponding signed and initialed PTO Form 1449 has been mailed with this action. The documents listed as an International Search Report, which is not considered to be a document under 37 CFR 1.98. Therefore, the International Search Report has been considered but has been crossed off the 1449 so that it will not appear on the face of any patent issuing from the instant application. Documents listed that have not been located have not been considered and have been crossed out. If applicants want the items listed in the IDS filed 12/12/03 to be considered, new copies of the articles should be sent, accompanied by a new Form 1449.

Claim Objections

Claims 7 and 19-21 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim 2 is objected to because of the following informalities: claim 2 recites “the E1 protein encoded by the aforementioned E1 region is rendered incapable of being expressed or is functionally defective. The claim recites that the deletions 1) result in loss of expression of the E1 gene products or 2) expression of a functionally defective gene product. For clarity it would be remedial to amend the claim to recite for example wherein the E1 region is deleted such that expression of E1A and/or E1B is lacking or the E1A and/or E1B gene product is functionally defective.

Claims 3 and 4 are objected to for recitation “wherein part of the E1 region is equivalent to the region between” are unclear. The claims are indicating that part of the genome that is partially deleted. For accuracy, it would be remedial to recite --wherein the partial deletion occurs in nucleotides-- as the term equivalent means “**something considered the same:** something that is considered to be equal to or have the same effect, value, or meaning as something else”. However, applicants intend that not something equal to but those sequences are deleted. Similar amendments to claim 6 are required.

Claim 12 is drawn to non-elected subject matter. If the claim is amended to incorporate the limitations of claims 8-11, care should be taken to incorporate those changes requested for currently examined claims.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 112 and 18-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in that the metes and bounds of the term “derived from” are unclear. It is unclear the nature and number of steps required to obtain a “derivative” of an adenovirus type 35 genome. The term implies a number of different steps that may or may not result in a change in the functional characteristics of the adenovirus type 35 vector from the source that it is “derived from”. The dependent claims are included in the rejection because they fail address or clarify the basis of the rejection as discussed in detail for the independent claims.

Claim 2 recites the limitation "the E1 protein encoded by the aforementioned E1 region" in claim 1. There is insufficient antecedent basis for this limitation in the claim. The claim recites “the E1 protein”, however there several gene products encoded by the E1 region and the claim does not set forth to which the E1 protein refers. As the claim does not set forth which E1 protein, the claim lacks antecedent basis.

Claim 6 is vague and indefinite in that the metes and bounds of “wherein part of the E3 region is equivalent to the region between nucleotides 2776 and 29,732” are unclear. This region encompasses much more than the E3 region and hence that can be no equivalents between the two.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5, 12 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by Bett et al (2004/0106194; see entire document).

Bett et al teach an Ad35 vector comprising a deletion in the E1 region in which the vector is deficient in E1 as well as deletion in the E3 region (see e.g. ¶ 65 and 73-80). Because the Office does not have the facilities for examining and comparing the applicant's product with the products of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed products and the products of the prior art (e.g. that the products of the prior art do not possess the same material structural and functional characteristics of the claimed product). See *in re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977). The product set forth in a product-by-process claim although produced by a different process, appears to be the same product as that recited in claims 12 and 18.

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Schraa et al (2001/0033833; see entire document).

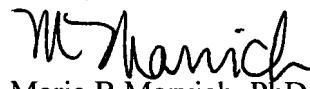
Schraa et al teach an Ad35 vector comprising a deletion in the E1 region in which the vector is deficient in E1 as well as deletion in the E3 region (see e.g. ¶ 61 and 63).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Maria B Marvich, PhD
Examiner
Art Unit 1633